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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,283	01/27/2004	Bal Ram Singh	08387-002003	3757

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/766,283	SINGH ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7,17-26 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,7,17-26 and 30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. In the preliminary amendment filed January 27, 2004, claims 2-6, 8-16, 27-29 and 31-32 have been cancelled. Therefore, claims 1, 7, 17-26 and 30 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U. S. C. 121:

I. Claims 1 and 7, drawn to a substantially pure polypeptide complex comprising a Clostridium botulinium neurotoxin and more than one Clostridium botulinium type E neurotoxin associated polypeptide, or a substantially pure Clostridium botulinium type E neurotoxin associated polypeptide, classified in class 530, subclass 350, and class 424, subclass 239.1.

II. Claims 17-21, drawn to an antibody specific binds to a Clostridium botulinium type E neurotoxin associated polypeptide or to a peptide complex comprising a Clostridium botulinium neurotoxin and more than one Clostridium botulinium type E neurotoxin associated polypeptide; or a method of detecting a serotype E neurotoxin complex in a sample using the antibody, classified in class 530, subclass 387.1.

III. Claims 22-24, drawn to a method of treating a patient who is suffering from a disease or condition associated with excessive release of acetylcholine from presynaptic nerve terminals, the method comprising administering to the patient a polypeptide complex, classified in class 530, subclass 350, and class 424, subclass 9.1.

IV. Claim 25, drawn to a method of treating a patient who is suffering from spasticity occurring secondary to brain ischemia, or traumatic injury of the brain or spinal cord, the

method comprising administering to the patient a polypeptide complex, classified in class 530, subclass 350, and class 424, subclass 9.1.

V. Claim 26, drawn to a method of treating a patient who is suffering from tension headache or pain, the method comprising administering to the patient a polypeptide complex, classified in class 530, subclass 350, and class 424, subclass 9.1.

VI. Claim 30, drawn to a method of detecting a Clostridium botulinium type E neurotoxin in a sample by contacting the sample with a Clostridium botulinium type E neurotoxin associated polypeptide, classified in class 530, subclass 350, and class 424, subclass 239.1.

3. The inventions are distinct, each from the other because of the following reasons:

The polypeptide of Invention I is related to the antibody of Invention II by virtue of being the cognate antigen, necessary for the production of the antibody. The inventions are distinct because they are physically and functionally distinct chemical entities and because the polypeptide can be used in another and materially different process from the use for production of the antibody such as to assay or purify the cognate receptor of the protein or in assays for the identification of agonists or antagonists of the receptor protein.

The product of Invention I is distinct from the method of Invention II because the product of Invention I can be neither made by nor used in the method of II.

The product of Invention I and the methods of Inventions III, IV, V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially

different process of using that product (MPEP § 806.05(h)). In the instant case, the methods of Inventions III, IV, V and VI are alternative processes of use of the product of Invention I.

The product of Invention II is distinct from the methods of Inventions III, IV, V and VI because the product of Invention II can be neither made by nor used in the methods of III, IV, V and VI.

The methods of Inventions II-VI are patentably distinct each from the other because they have different method steps, utilize different materials and produce different results.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter, and because each invention requires different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection

are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CHIH-MIN KAM
PATENT EXAMINER

CMK
March 16, 2006